

REMARKS

This Amendment is being filed in response to, and within three (3) months of, the Office Action mailed April 13, 2006. Applicant previously elected Claims 1-8, withdrew Claims 9-26, and added Claims 27-35. Accordingly, Claims 1-8 and 27-35 are pending.

GENERALLY

Initially, Applicant would like to thank Examiner Fidei for holding a telephone interview with Applicant's counsel, Vic Lin, on May 15, 2006. Applicant is also appreciative of the fact that the outstanding second Office Action is non-final. Applicant has not provided a written Interview Summary herewith due to the courtesy of Examiner Fidei's promised Interview Summary.

CLAIM REJECTIONS – CLAIMS 1-8, 27-35 – 35 USC § 112, 1st Paragraph

Claims 1-8 and 27-35 were rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification. As discussed during the May 15th interview, support for the non-peelable aspect of the bonding between the coils is found throughout the specification, including:

- page 4, lines 1-4: "A thermal weld bonds the first coil portion to the second coil portion in a fixed relationship, and provides a strength sufficient to prevent peeling the first coil portion from the second coil portion."

- page 4, lines 23-25: "By bonding the adjacent coiled portions at the heating (thermal transfer) station, the coiled configuration of the tube can be permanently maintained."
- page 8, lines 3-5: "The process of thermally bonding the tubing together is applied to join singular or a plurality of tubes to form a coiled packaging, holding and dispensing tube ("packaging tube") that is not intended to be separated."
- page 9, lines 19-20: "These bonds 30 maintain the coils 52, 54, and 56 in a fixed relationship so that they cannot be separated or peeled."
- page 10, lines 3-5: "As the materials of the various elements are heated, they tend to plasticize, conjoining the surfaces of the elements in a fixed, non-peelable relationship."

Applicant respectfully submits that ample support for the "non-peelable" recitation is found in the specification.

CLAIM REJECTIONS – CLAIMS 1-8, 27-35 – 35 USC § 112, 2nd Paragraph

With respect to the language concerning the manual force by a user's hand and the package being rendered useless should the coiled portions be detached, Applicant has herein deleted that language from the claims. The original intent of this language was not to cause ambiguity, but rather to prevent an infringer from ripping apart a copycat device with excessive force and then arguing that its device does not infringe because it can be peeled. Thus, the purpose of the prior amendment was to facilitate

clarity, not confusion. Nonetheless, Applicant has removed said language pursuant to the examiner's requirements in order to further this application along.

The "non-peelable" recitation has been left in the claims in a manner consistent with the disclosures in the specification as set forth above.

CLAIM REJECTIONS – CLAIMS 1-8, 27-35 – 35 USC § 103(a)

A. Applicant Is The First to Create a Non-Peelable Coiled Packaging Without Clips Using a Thermal Weld

Claims 1-8 and 27-35 were rejected under under 35 USC § 103(a) as being unpatentable over Prather et al (US 5,247,942) in view of Globensky et al. (US 6,511,573).

Prior to discussing the cited prior art, a few significant points bear emphasis.

First, Applicant recognizes that the prior art includes coiled packaging for surgical devices, and that such prior art packaging include structures which are not intended to be separated or peeled. Applicant is not claiming to invent the first non-peelable coiled packaging. It is in how Applicant's claimed invention accomplishes a non-peelable coiled packaging that is new and unique, and is not disclosed in the cited art of record thus far.

Second, Applicant recognizes that mechanical clips have been employed in the past for this purpose. While clips in prior art packaging are meant to keep the coils together, the problem with prior art clips, however, is that they "have been formed with sharp edges and points, which have tended to puncture the pouch thereby

compromising the sterility of the device” as stated in the specification in the Discussion of the Prior Art and Related Information, page 2, lines 9-18. In medical and surgical applications where sanitation cannot be compromised, a damaged package for a guidewire, for example, would be a complete waste. Obviously, this is not a problem or expense that can be taken lightly. As Applicant explained in the prior art discussion in the specification, mechanical clips in the prior art are also labor intensive and time consuming to apply.

All of these foregoing deficiencies associated with clipped packages in the prior art have been overcome with Applicant's coiled packaging which does away with mechanical clips. Applicant's claimed invention is directed to a clipless coiled packaging, if you will, wherein the coiled configuration of the package is maintained in a non-peelable relationship with thermal welds that couple adjacent surfaces of the coils together. No secondary material, such as adhesives, are utilized since the coils are composed of a common material which plasticizes and conjoins the surfaces of the tubing coils together so that they cannot be separated. Thus, mechanical clips and all their problems associated are completely omitted.

Applicant has also amended dependent Claim 2 to recite that the thermal weld is continuous, which reinforces the non-peelable feature of the coiled package.

B. Applicant's Invention Is Not Obvious In View of the Cited References

1. The Cited Combination

Turning now to the cited prior art references, the Office Action states that Prather “discloses a package for an elongate surgical device comprising an elongate tube 16

held in a coiled condition by clips 18 or any other suitable means, col. 4, lines 43, 44.”

The Office Action acknowledges that Prather does not disclose a “weld bond fixing a first coiled portion to a second coil[ed] portion of the coil.”

The Office Action then turns to Globensky and states that this reference discloses holding adjacent tubes by a “weld bond” where a filler material is melted to a liquid state and hardens as a fastener, e.g., see col. 4, lines 43-51.

Accordingly, the issue here is whether a prima facie case of obviousness can be established with the cited references, Prather and Globensky. To establish a prima facie case of obviousness, three basic criteria must be met:

- 1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;
- 2) there must be a reasonable expectation of success; and
- 3) the prior art reference(s) must teach or suggest all the claim limitations.

MPEP § 2142.

Obviousness requires all three (3) of the above factors to be met. Thus, the absence of merely one of the above factors is sufficient to preclude a case of obviousness. Here, Applicant respectfully submits that a prima facie case of obviousness cannot be established with the cited combination because at least two of the three criteria are absent in the cited combination.

2. The Cited Combination Does Not Teach or Suggest All the Claim Limitations

The cited combination does not teach or suggest all the limitations now recited in the claims amended herein. As amended, the subject claims now recite, in one format or another, that the first coiled portion and the second coiled portion are composed of the same material. For example, Claim 1 recites that the first coiled portion is composed of a plastic material and that the second coiled portion is also composed of the plastic material. Independent Claim 27 recites that the first coiled portion and the second coiled portion are composed of a common material. Independent Claim 33 also recites that the first, second, third and fourth coiled portions are all composed of a common material.

Having the coiled portions composed of the same material is important for the feature recited in all the independent claims – that the coiled portions are thermally welded to each other. In particular, no secondary materials or mechanical components, such as adhesives or clips, are utilized or even necessary to accomplish the bond. The claimed weld between adjacent surfaces of Applicant's coiled packaging is a true weld in the sense that the same material of the adjacent coiled portions is being thermally welded so as to plasticize and conjoin together to form a non-peelable relationship.

This feature is not disclosed or suggested in the cited combination. Prather discloses a mechanical clip that is representative of the prior art and all the deficiencies associated therewith. The combination of Globensky with Prather nonetheless fails to disclose all the claimed limitations.

As acknowledged in the Office Action, Globensky teaches an adhesive material, or adhesive tabs, 80 that hold the coiled tubing together. While the adhesive material 80 is heated to a liquid state, this fact alone does not make the connection between the tubing a thermal weld.

In Applicant's claimed invention, the bond between the coils is a thermal weld wherein the same material comprising the coils is plasticized and conjoined without any secondary materials. Applicant's thermal weld obviates the need for any secondary materials such as adhesives.

Furthermore, dependent Claims 2 and 31 recite that the thermal weld is continuous. Prather altogether fails to show any welds. Globensky also fails to show a weld composed of the same material between adjacent coils. Nonetheless, even if Globensky's adhesive material 80 is to be loosely interpreted as a weld because it is melted into liquid form at a particular stage, Globensky does not disclose or suggest a continuous weld between the coiled portions. In fact, Globensky teaches away from a continuous weld because the adhesive material, or tabs, are necessarily formed as patches which are intermittently adhered to various parts around the coiled package as shown in Figure 1.

3. No Motivation or Suggestion to Combine or Modify or Combine
References

The cited combination of Prather and Globensky begs the following questions:

- 1) How can a reference which teaches the use of mechanical clips in a coiled package motivate or suggest a package without clips?; and
- 2) How can a reference which teaches the use of a secondary adhesive material to join coils motivate suggest a package that obviates the need for the secondary adhesive material?

The answer to both questions is that they simply do not.

A closer examination of Prather reveals that the reference is primarily directed to a two-part intravascular guide wire having a "main part 10" to an "extension part 12," and, in particular, the coupling of the main part 10 to the extension part 12. In other words, Prather's invention is directed to the guide wire itself, and not to the packaging containing the wire. Prather is completely unconcerned with the coiled packaging, and understandably so, since the invention disclosed therein is entirely directed to a new type of guide wire that would solve the problem of exchanging conventional guide wires in complex procedures such as those involving the coronary vasculature (col. 2:14-63). As shown in Figures 1-2 of Prather, the focal point of the invention is directed to the coupling of the main part and extension part of the guide wire which obviously lies outside of the coiled packaging. The disclosure of the coiled packaging in Prather is merely a matter-of-fact statement to the effect that the guide wire may be "held in a carrier tube 16" (col. 4:37) such as "for shipping, etc." (col. 4:48).

Prather has absolutely no aspiration of creating a new type of coiled packaging or a new way of holding coils together. The statement in column 4, lines 41-43 that the coiled orientation may be held by "cavity clips 18 or any other suitable means" is nothing

more than a common writing tool that patent attorneys/agents employ to make it clear that the coiled orientation is not limited to a clip. This matter-of-fact statement, however, is a far cry from suddenly rendering obvious all new methods and structures for coiled packaging, especially when the reference clearly has no teaching or motivation directed to the packaging.

Even, assuming for the sake of argument, there was something in Prather to motivate or suggest a combination, the cited combination with Globensky is faulty. Globensky teaches the use of a secondary material, namely an adhesive material, to hold coils together. Accordingly, Globensky teaches away from Applicant's claimed invention because Applicant's device completely obviates the need for any secondary materials. Again, the proposed combination with Globensky cannot be made without confronting the cornerstone question – How can a reference which is entirely directed to the use of a unique adhesive material/structure to hold coils motivate or suggest a device that entirely omits the unique adhesive material/structure?


It is in the omission of clips and secondary materials that makes Applicant's claimed structure entirely unique, and this omission is accomplished by thermal welds of the same material of which the coiled portions are composed. Not only do the cited references fail to teach this feature, the references provide no motivation or suggestion for a combination that would arrive at this feature.

Accordingly, Applicant respectfully submits that independent Claims 1, 27 and 33 are allowable over the cited prior art references. Applicant further submits that the dependent claims are allowable for the additional features recited therein.


Applicant encourages the Examiner to telephone the undersigned attorney if it appears that a telephone conference would facilitate allowance of the application.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 8, 2006

by Eric Hoover


Signature

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